Tissue ID Number:

Place Sticker Here

STERILE HUMAN ALLOGRAFT: INSTRUCTIONS FOR USE

DESCRIPTION

OsteoFactor Allogeneic Proteins is an allograft derived from DONATED HUMAN TISSUES. The tissue was prepared from a donor determined to be suitable for transplant by Precision Allograft Solutions (PAS)/Alamo Biologics LLC (AB) Medical Director based on the results of screening and testing. Recovery was performed using sterile surgical procedures; PAS/AB's controlled tissue processing environment is designed to ensure tissue allograft bio-implant quality and safety. Implant Innovations' processing uses stringent aseptic techniques prior to terminal sterilization via gamma irradiation. This allograft was prepared with storage agents consisting of Sucrose, Glycine, L-Glutamic Acid, Sodium Chloride, and Polysorbate-80.

STORAGE

This product should be stored at ambient temperature 11.0-30.0°C (51.8-86.0°F) until the expiration date shown on the allograft label. The user facility and clinician are responsible for maintaining allograft tissue in appropriate storage conditions prior to transplant.

INSTRUCTIONS FOR PREPARING ALLOGRAFT FOR ADMINISTRATION

Prior to surgery, carefully follow the tissue preparation steps as described below:

Note: OsteoFactor Allogeneic Proteins are lyophilized and packaged in a double sterilized pouch with the inner pouch designed to be passed directly into the sterile field.

1. Remove pouch, IFU, labels and Tissue Tracking Record from the box.
2. Attach a peel-off label with tissue ID number to patient records.
3. Fill out the Tissue Tracking Record by providing patient information, the transplantation facility name and address, and comments regarding tissue. Return the completed form to Implant Innovations and retain a copy in the patient medical record.
4. Using aseptic technique, peel back the outer Poly/Poly pouch and introduce the inner Poly/Poly pouch into the sterile field.
5. Peel back the inner Poly/Poly pouch and remove the vial.
6. Remove only the red cap from vial, and inject sterile water **OR** sterile saline with a needle and syringe through the rubber stopper.
   Note: Refer to the following table for reconstitution volume:

OsteoFactor Allogeneic Proteins Size	Suggested Reconstitution Volume
Small	1cc
Medium	2.5cc
Large	5cc
Xlarge	10cc

7. Gently swirl and invert the vial to ensure adequate mixing.
8. Remove the metal ring by pulling up and out; then remove the rubber stopper.
9. Uniformly distribute reconstituted liquid onto a scaffold.
10. Allow a minimum of 15 minutes for growth factors to bind to the scaffold.
11. Once the vial seal has been compromised, the product shall be used or discarded.

TREATMENT WITH GAMMA IRRADATION

Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize any bioburden contamination. All PAS/AB tissues are procured via a network of qualified and trained recovery partners that use stringent screening and recovery protocols. Implant Innovations utilizes tissue cleaning and validated sterilization processes, and a highly controlled processing environment, thus minimizing the risk of disease transmission at every step. Subsequently, all allografts are terminally sterilized using gamma irradiation with a dose between 15-22kGy to ensure patient safety.

INDICATIONS AND USAGE

OsteoFactor Allogeneic Proteins may be used in situations where bone graft and/or autograft is appropriate, such as spinal fusion procedures. It should be restricted to homologous use for the repair, replacement, or reconstruction of musculoskeletal defects.

- Intended for use in one patient on a single occasion only.
- Only qualified health care professionals (e.g. physicians, dentists, podiatrists, etc.) should transplant donated human tissue.
- Tissue may not be re-sterilized.
- Human tissue for transplantation shall not be offered, distributed or dispensed for veterinary use.
- PAS/AB, Implant Innovations, and Xtant Medical assume no responsibility for the clinical use of this allograft tissue.
- Tissues may transmit infectious disease agents. Any adverse outcomes that may be attributable to the implantation of this allograft tissue must be reported to Xtant Medical immediately.

DONOR SCREENING AND TESTING

Donor risk assessment is performed at the time of donation according to U.S. Public Health Service guidelines, including discussions with healthcare professionals and/or family members, to identify circumstances which may lead to the exclusion of the deceased from the donor population. All tissue is recovered under appropriate conditions from carefully screened donors. A blood sample from the donor is tested by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and 42 CFR part 493 using, when available, FDA-licensed test kits. Precision Allograft Solutions/Alamo Biologics only releases tissue for transplantation that has negative or non-reactive results for:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus by TMA
- HIV-1 NAT: Human Immunodeficiency Virus type 1 by TMA
- HBV NAT: Hepatitis B Virus by TMA
- RPR/STS or Equivalent: Syphilis

* Additional tests, including, but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.

In some instances, postmortem autopsies and/or biopsies are performed as a screen for nonspecific infectious or malignant conditions. Tissue is carefully examined at the time of recovery, and again during processing to ensure that it is suitable for a variety of transplantation applications. Serology test results, medical history, physical assessment, available relevant medical records including previous medical history, laboratory test results, existing autopsy or coroner reports, as well as information

from other sources or records which may pertain to donor eligibility, along with tissue procurement test results, have been evaluated by PAS/AB Medical Director. The results are sufficient to indicate that the donor eligibility criteria current at the time of tissue recovery have been met. Donor risk assessment, tissue-related information, and tissue processing details shall be made available to the end-user upon request, except such information that may infringe upon the confidentiality of donor information.

PRECAUTIONS

Because of potential violations of sterility, this allograft must not be transplanted under the following conditions:

- The container in which the product is stored is damaged compromising packaging integrity.
- The tissue's outer packaging is damaged or missing.
- The expiration date has been exceeded.
- The allograft is not labeled, or the label's information is damaged, defaced or illegible.
- The allograft has not been stored according to acceptable storage conditions outlined in this Package Insert.
- If any of the allograft or package elements appear to be missing, damaged or tampered with.
- If the product label or identifying barcode is severely damaged, illegible or missing.

If any of the conditions mentioned above exist or are suspected, please notify Xtant Medical immediately for resolution.

CONTRAINDICATIONS, SIDE-EFFECTS, AND HAZARDS

No contraindications are known to exist. Sucrose, Glycine, L-Glutamic Acid, Sodium Chloride and Polysorbate-80 are present, and caution should be exercised if the patient is allergic to any of these agents. A relative contraindication would include the presence of infection in the host bed where the allograft is implanted. Limitations of allografts include slow and/or incomplete incorporation and/or resorption that may be due to the difference in histocompatibility factors between the donor and recipient. Bacterial infection at the site of implantation may occur. This complication may not be apparent for long periods of time (6-24 months) after transplantation. Transmissions of infectious disease may occur despite rigorous donor selection and testing.

COMPLICATIONS AND POSSIBLE ADVERSE REACTIONS

Inherent uncertainties exist in medical and social histories and lab testing that may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Transmission of disease of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi;
- Immune rejection of implanted HCT/P; or
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Report any adverse outcomes to Xtant Medical immediately.

HCT/P TRACKING

Per 21 CFR 1271.290(e), documentation about the tissue disposition to enable tracking from the donor to the consignee or final disposition must be maintained. Once the tissue is used (implanted) in a patient, it is critical that the organization that implants the tissue returns the tissue usage information card(s) requested by source facilities. To comply with these requirements, a Tissue Transplant Record (TTR) and pre-printed labels with every graft are provided. Record the patient information, the transplantation facility name and address, and comments regarding tissue on the TTR. Return the completed form to Implant Innovations and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification information and reason for discard needs to be returned to Implant Innovations.

RETURN POLICY

If for any reason tissue must be returned, a return authorization is required from Xtant Medical prior to shipping.

DONOR ELIGIBILITY AND PRE-PROCESSING BY:
Precision Allograft Solutions / Alamo Biologics LLC
5844 Rocky Point
San Antonio, TX 78249
(210) 738-2663

PROCESSED, PACKAGED, AND STORED BY:
Implant Innovations
1905 Aston Ave. Suite 101
Carlsbad, CA 92008
(800) 207-4975

MARKETED AND DISTRIBUTED BY:
Xtant Medical Holdings, Inc.
664 Cruiser Lane
Belgrade, MT 59714
888.886.9354

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant, and that recipient records must be maintained for the purpose of tracing tissue post-transplantation. PAS/AB, Implant Innovations, and Xtant Medical will not be liable for any damages, whether direct or indirect, special, incidental, or consequential resulting from improper use of this allograft. The instructions for use are specific, PAS/AB, Implant Innovations, and Xtant Medical waive all responsibility associated with mishandling, inappropriately storing, and/or not taking proper precautions with the allograft tissue included with this insert.